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(54) **ACTIVE FIXATION LEAD HAVING A ROTATABLE CURVE**

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A61N 1/375 (2006.01)

(52) **U.S. Cl.**
CPC ***A61N 1/059*** (2013.01); ***A61N 1/0573*** (2013.01); ***A61N 1/3752*** (2013.01); *A61N 1/056* (2013.01)

(58) **Field of Classification Search**
CPC A61N 1/0488; A61N 1/056; A61N 1/057; A61N 1/059; A61N 1/3752; A61N 1/0573
USPC 607/119, 122, 126, 116
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,141,593 A * 10/2000 Patag 607/122
6,212,434 B1 4/2001 Scheiner et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0180348 B1 5/1986

OTHER PUBLICATIONS

International Search Report and Written Opinion issued in PCT/US2013/073103, mailed Feb. 25, 2014, 9 pages.

(Continued)

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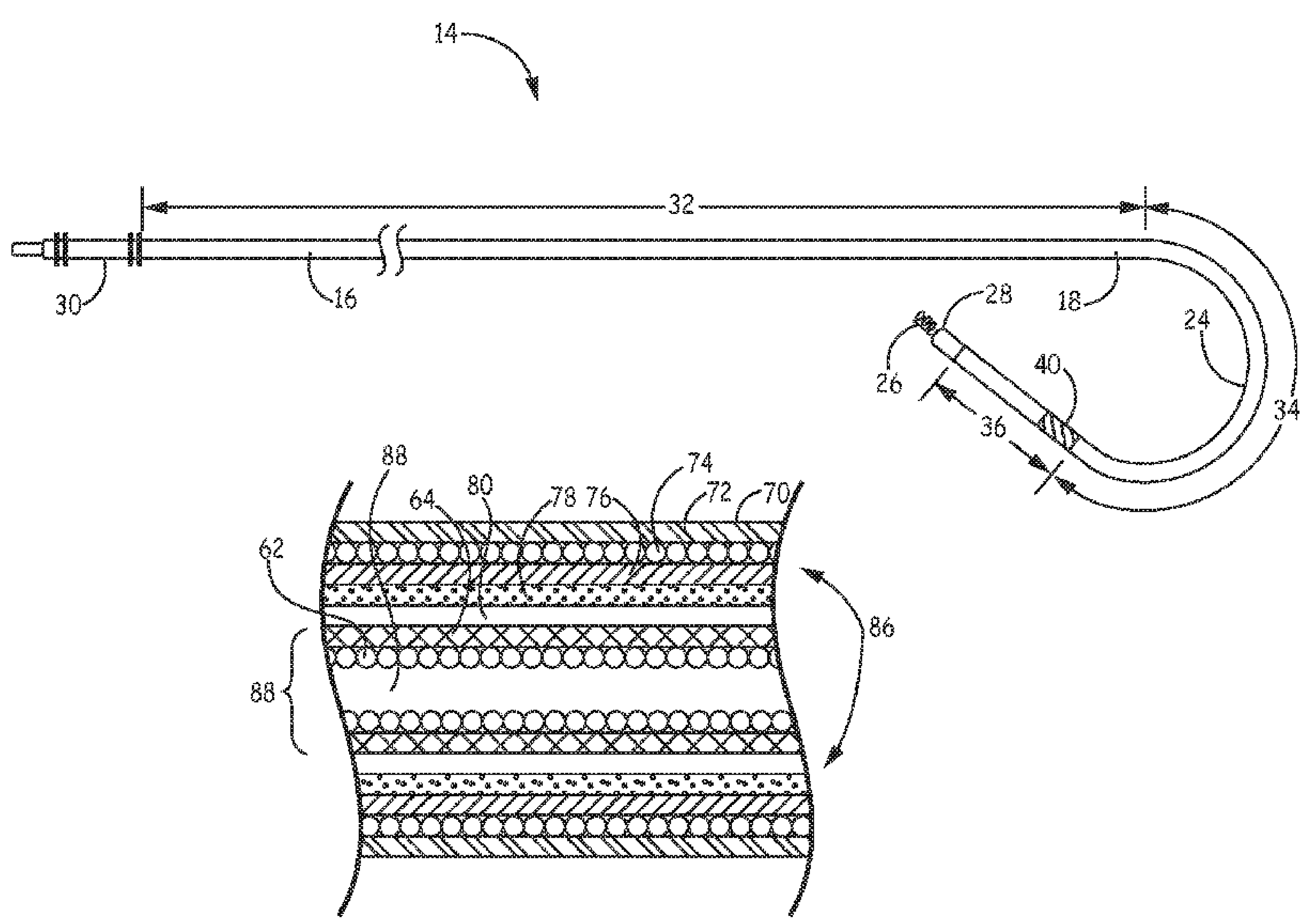
(57) **ABSTRACT**

Various embodiments concern a lead having a proximal section and a curbed section. The lead can comprise an outer tubular portion having a bias such that the lead assumes a curved shape along the curved section. The lead can further include an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner tubular member stiffer along the proximal section than the curved section, the outer tubular portion stiffer along the curved section relative to the inner tubular portion along the curved section such that the inner tubular portion can rotate relative to the outer tubular portion while the curved shape is substantially maintained. Relative rotation can extend and rotate and active fixation element.

20 Claims, 5 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

6,463,334	B1	10/2002	Flynn et al.	
7,558,632	B1 *	7/2009	Salys	607/125
8,494,651	B2	7/2013	Hearer et al.	
2007/0299493	A1	12/2007	Osypka	
2011/0093053	A1 *	4/2011	Djurling	A61N 1/056 607/116
2011/0160825	A1	6/2011	Haarer et al.	

OTHER PUBLICATIONS

International Preliminary Examination Report issued in PCT/US2013/073103, completed Jun. 9, 2015, 7 pages.

* cited by examiner

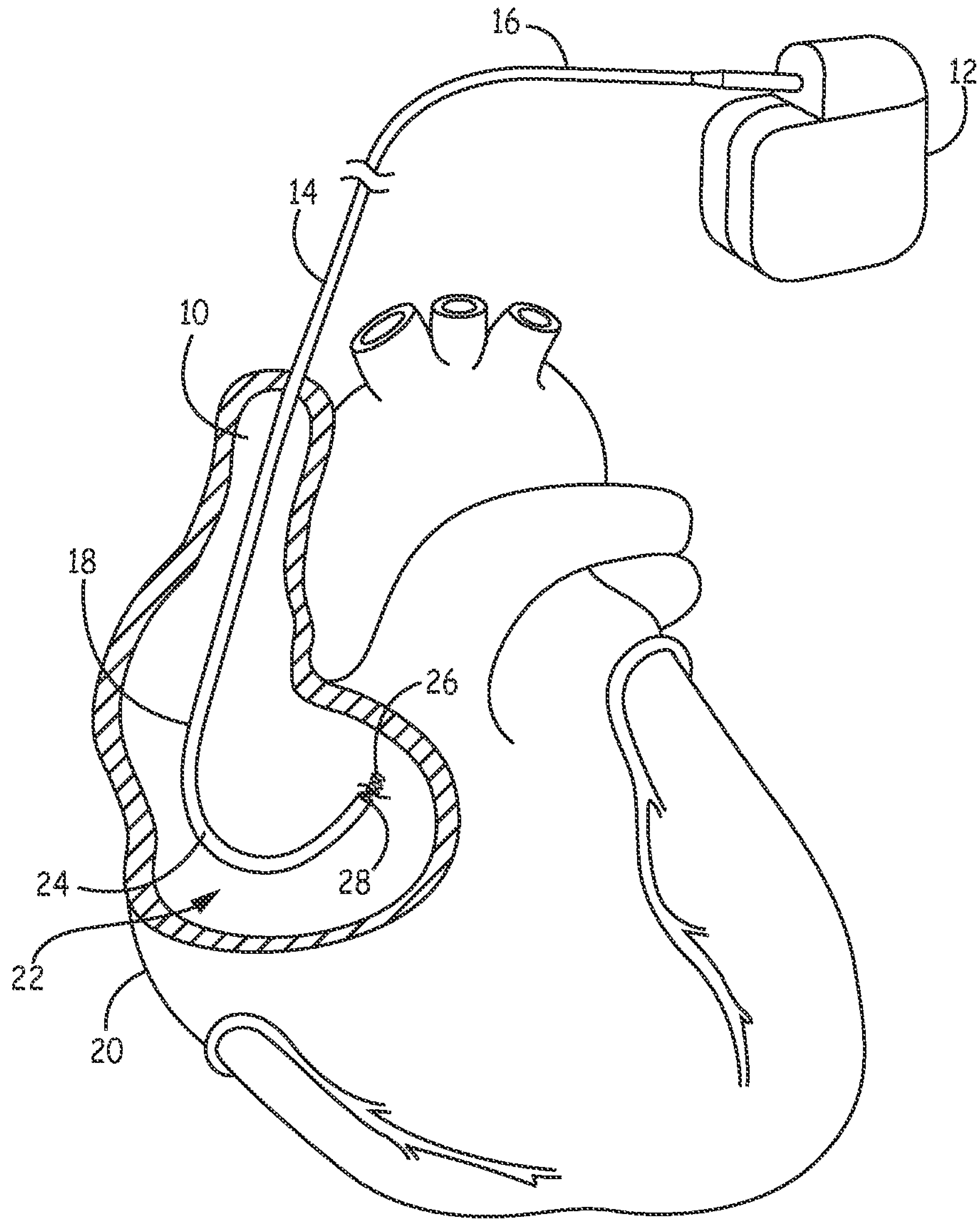


FIG. 1

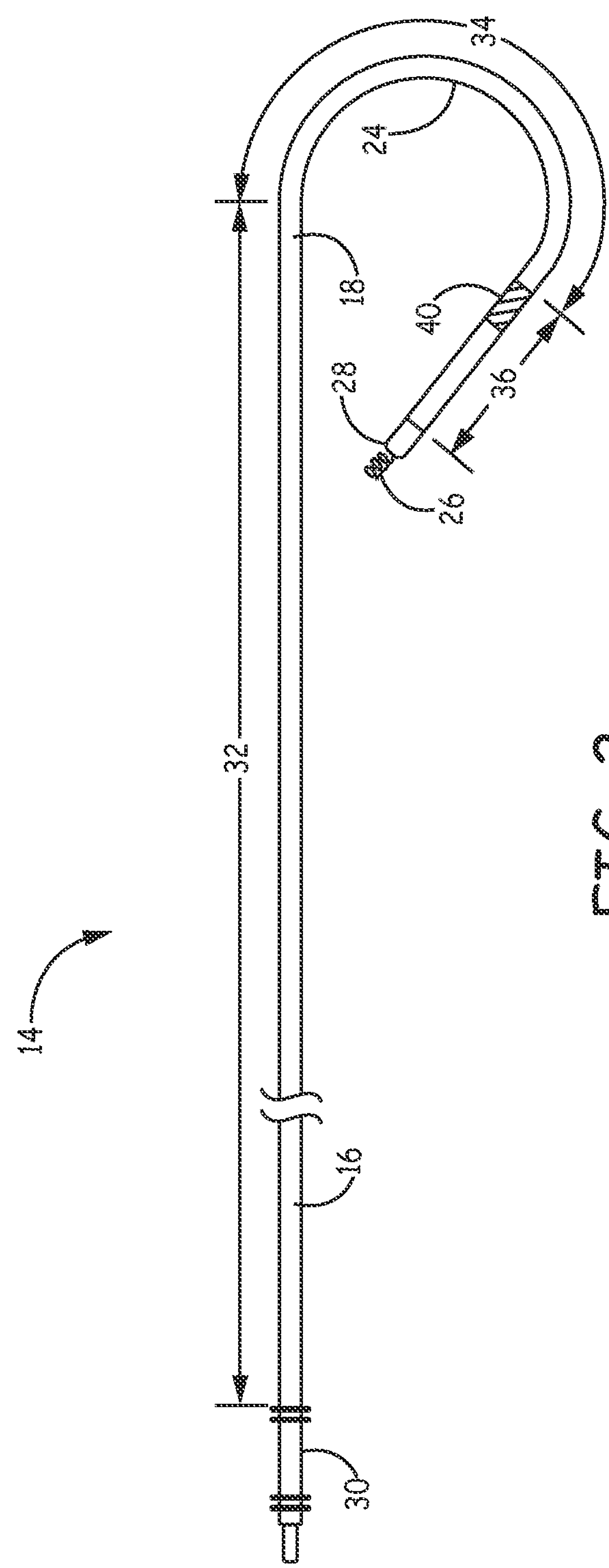


FIG. 2

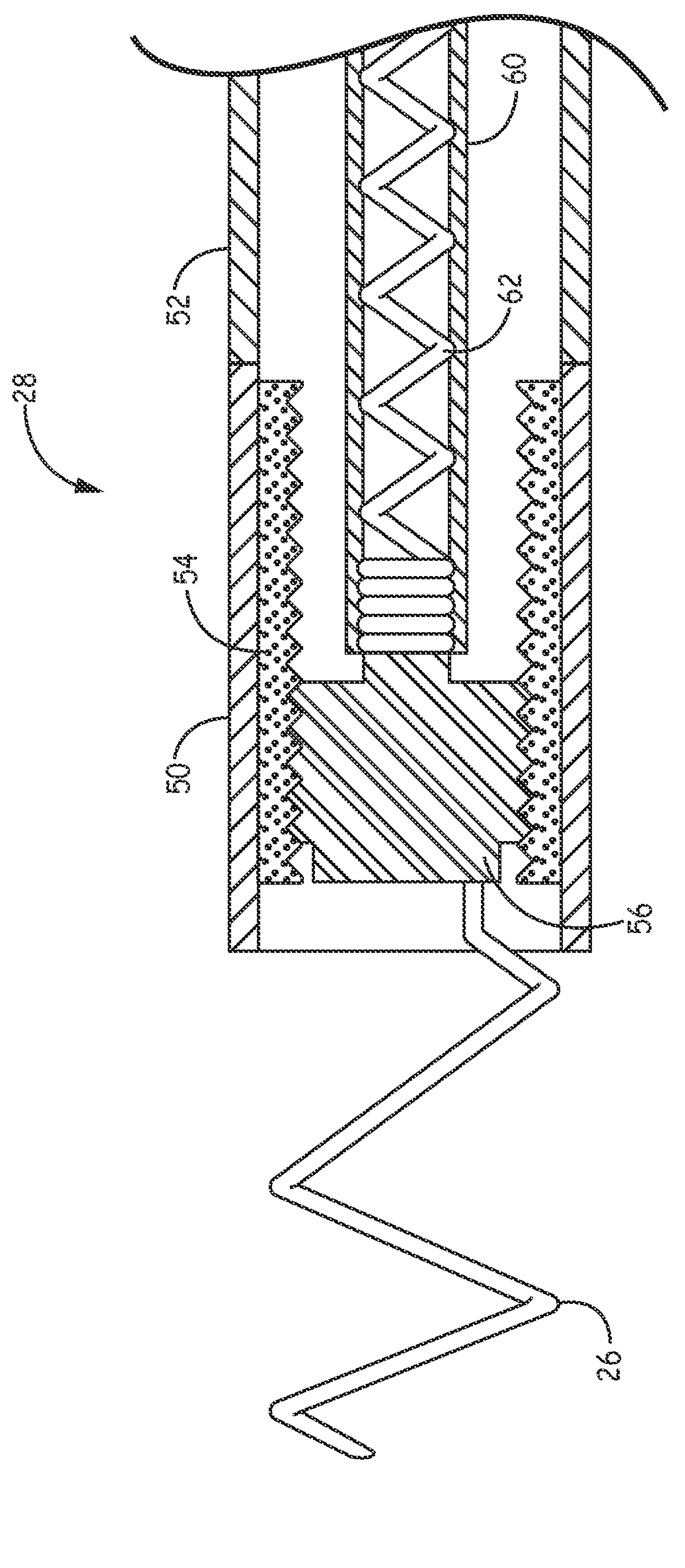


FIG. 3

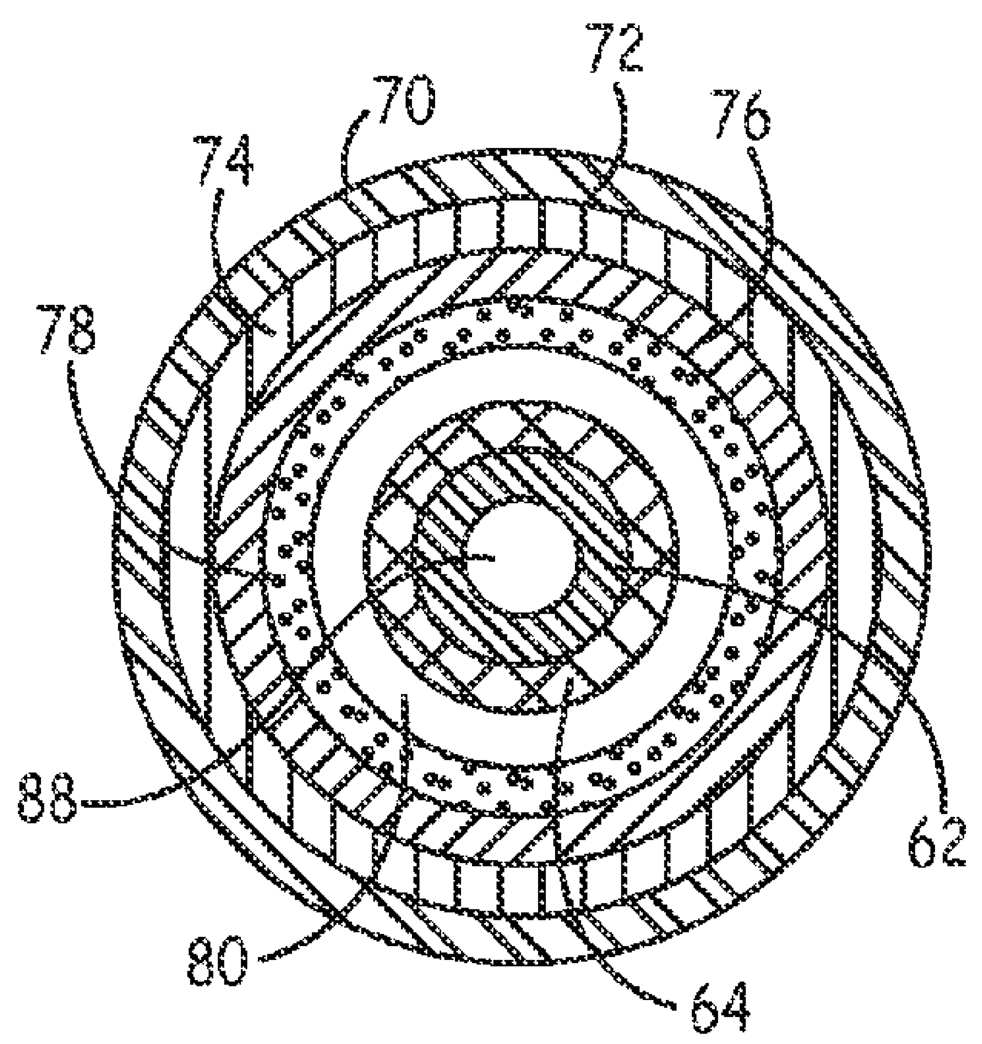


FIG. 4A

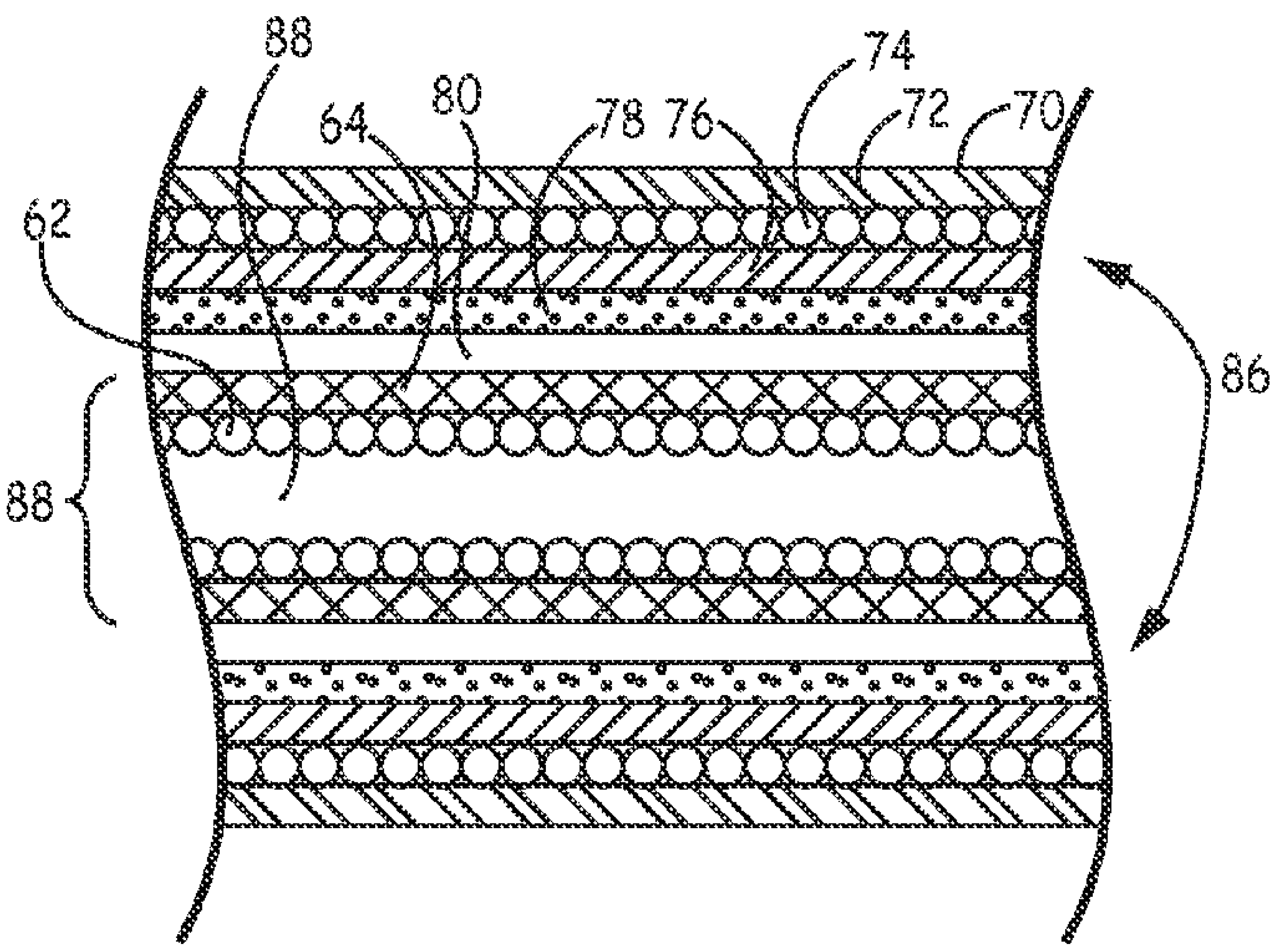


FIG. 4B

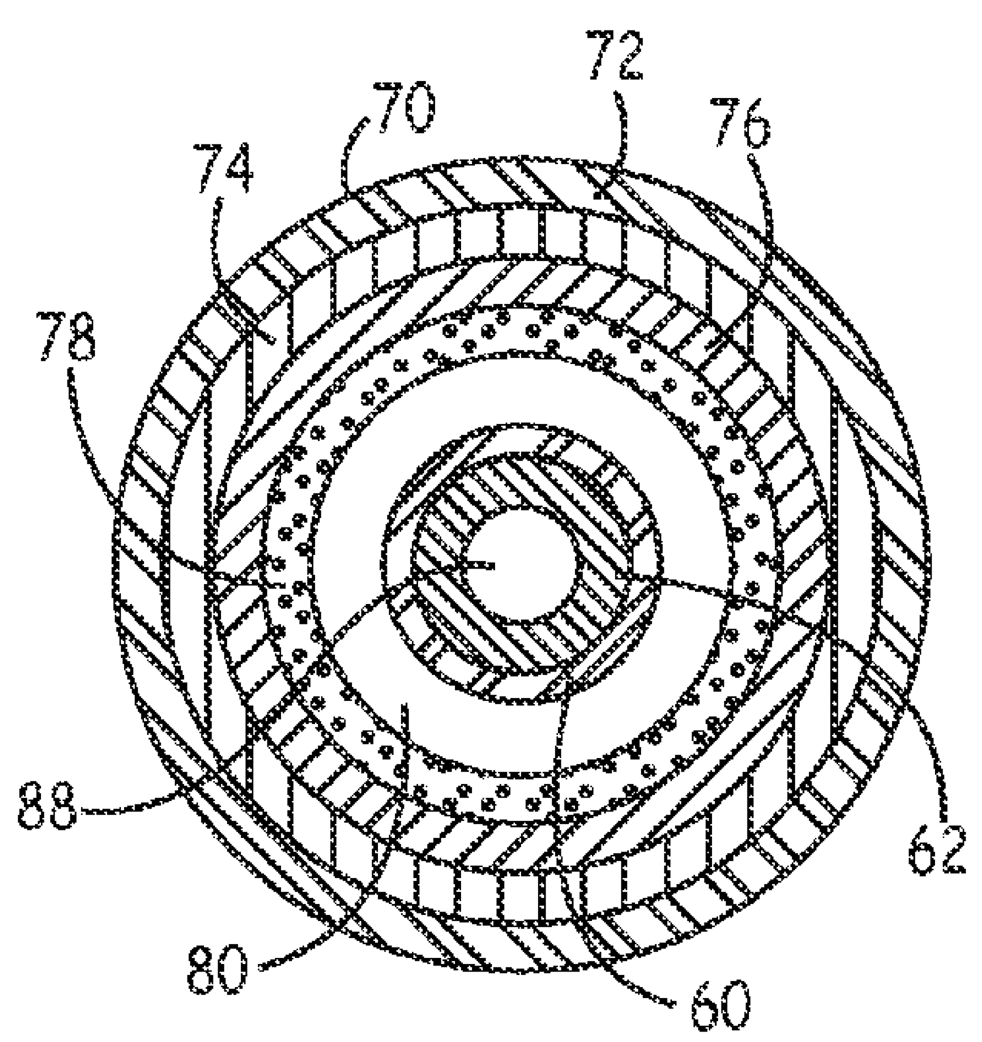


FIG. 5A

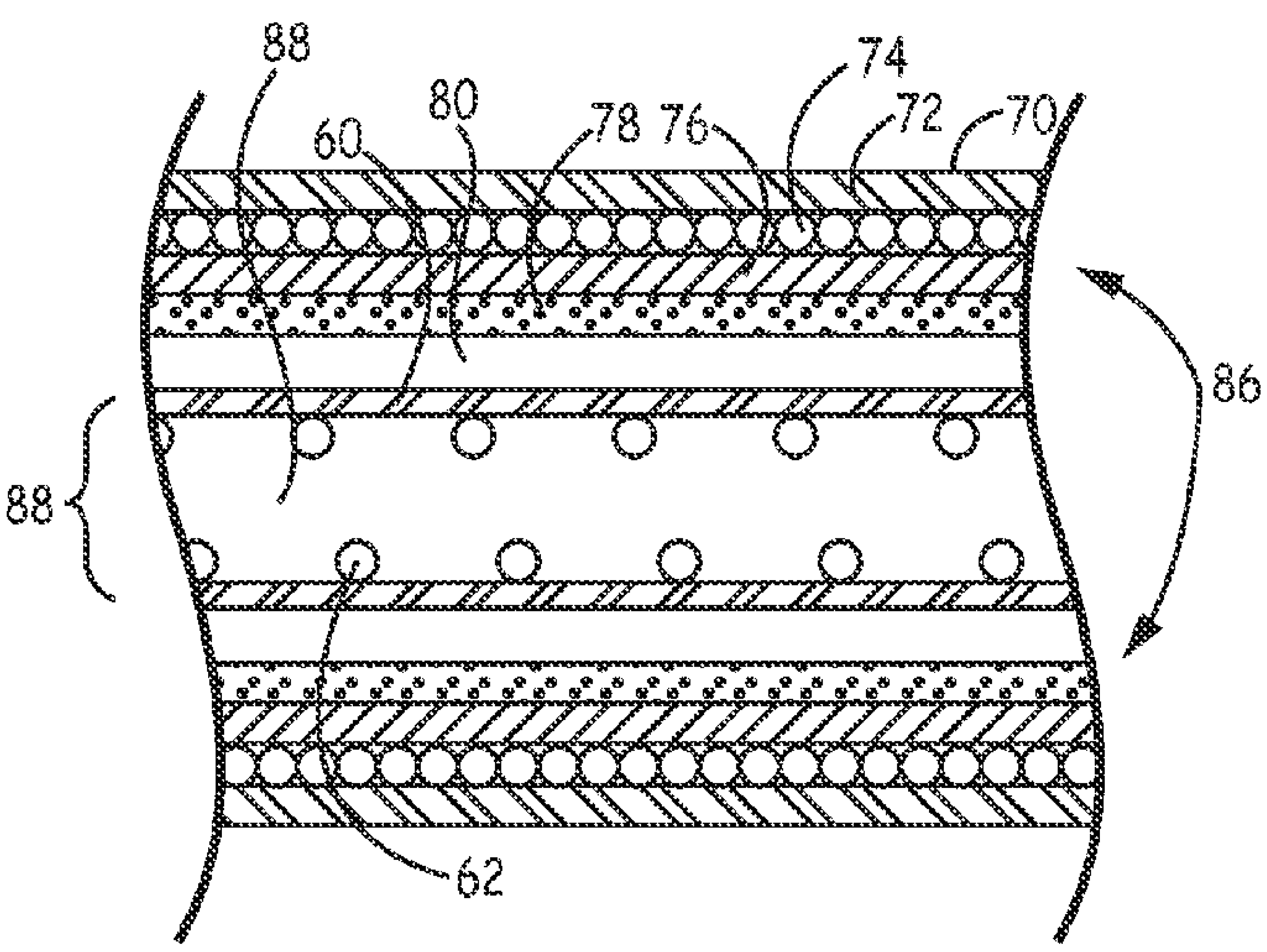


FIG. 5B

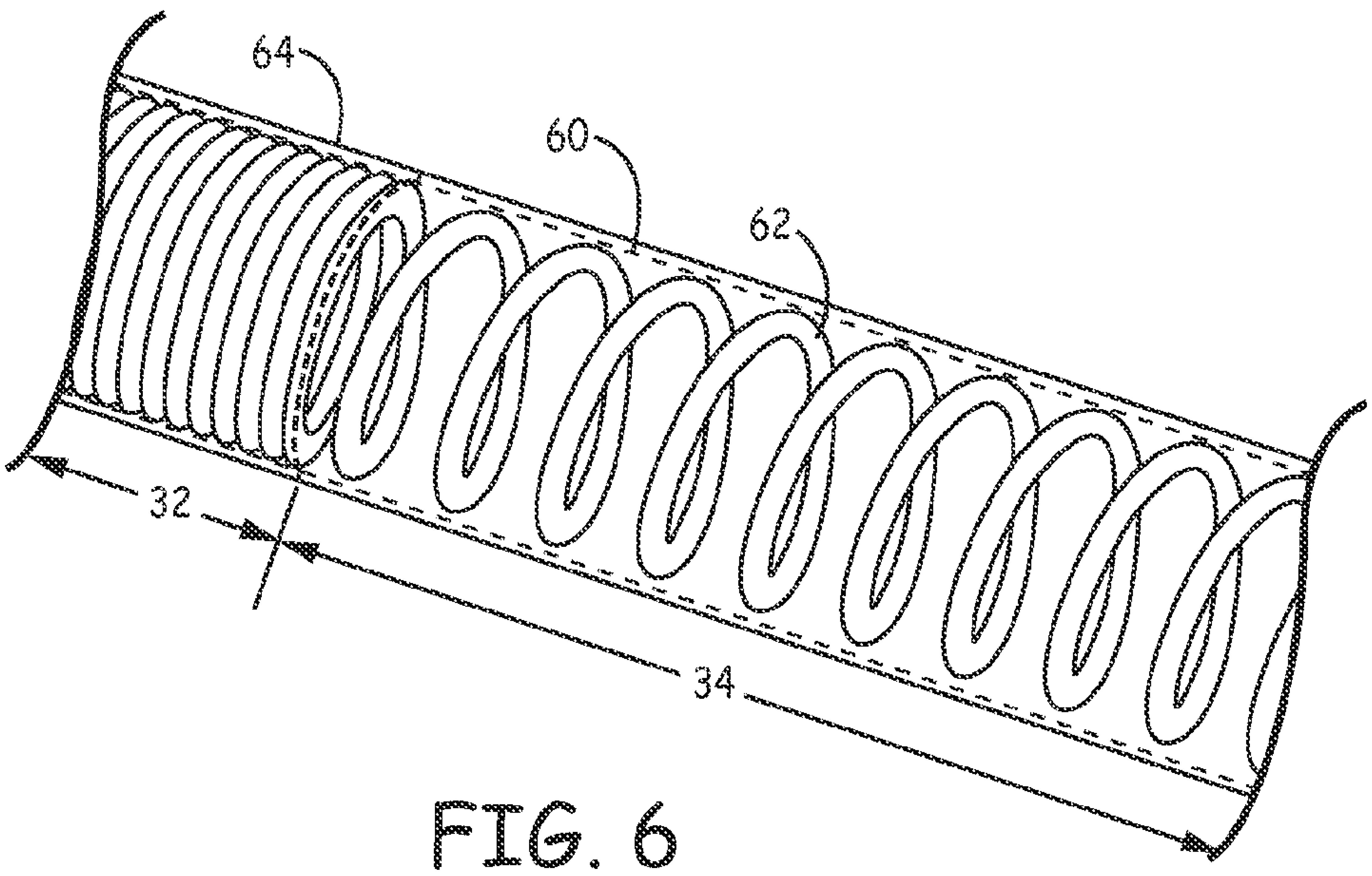


FIG. 6

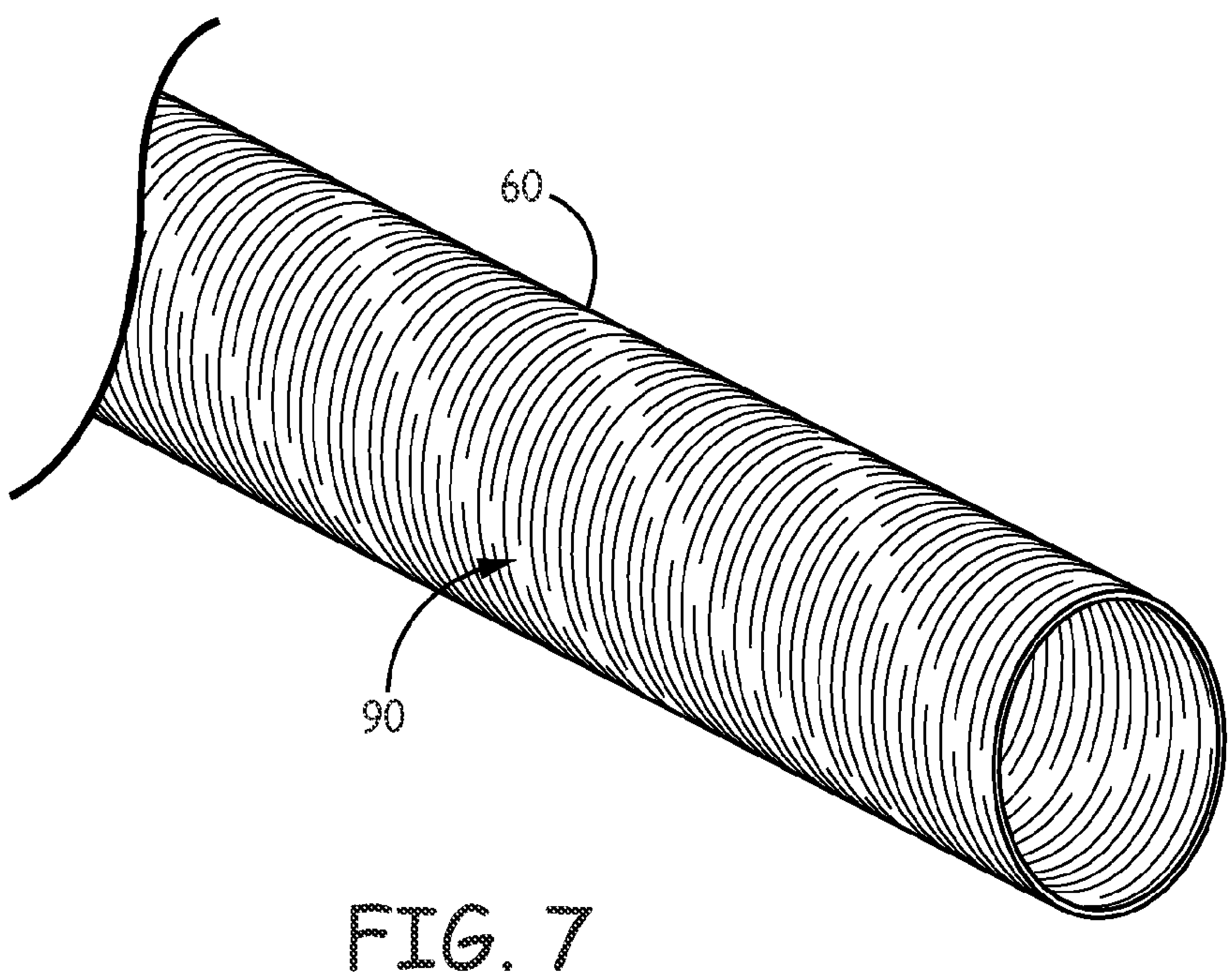


FIG. 7

ACTIVE FIXATION LEAD HAVING A ROTATABLE CURVE

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application 61/733,524, filed Dec. 5, 2012, which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

The present disclosure relates generally to implantable medical leads. More specifically, the disclosure relates to leads having biased shapes.

BACKGROUND

When functioning properly, the human heart maintains its own intrinsic rhythm and is capable of pumping adequate blood throughout the body's circulatory system. However, some individuals have irregular cardiac rhythms, referred to as cardiac arrhythmias, which can result in diminished blood circulation and cardiac output. One manner of treating cardiac arrhythmias includes the use of a pulse generator (PG) such as a pacemaker, an implantable cardioverter defibrillator (ICD), or a cardiac resynchronization (CRT) device. Such devices are typically coupled to one or more implantable leads having one or more electrodes that can be used to deliver pacing therapy and/or electrical shocks to the heart. Implantable leads can additionally or alternatively be used to stimulate other nervous and/or musculature systems of the body.

SUMMARY

Example 1 concerns an implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising: an outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section; an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner coil conductor extending from the proximal section to the distal section and having a steeper filar pitch along the curved section than along the proximal section, the inner polymer jacket having a plurality of slots along the curved section that increases the flexibility of the inner tubular portion; and an active fixation element on the distal end, the active fixation element in electrical connection with the inner coil conductor, the active fixation element configured to affix to tissue by rotation of the inner tubular portion relative to the outer tubular member.

In example 2, the lead of example 1, wherein the outer tubular portion is stiffer than the inner tubular portion along the curved section such that the curved shape of the implantable lead is substantially maintained during rotation of the inner tubular portion relative to the outer tubular portion.

In example 3, the lead of either of examples 1 or 2, wherein the inner tubular portion is relatively stiffer along the proximal section and less stiff along the curved portion.

In example 4, the lead of any of examples 1-3, wherein the inner polymer jacket inhibits radial expansion of the inner coil conductor during rotation of the inner tubular portion.

In example 5, the lead of any of examples 1-4, wherein the inner coil conductor has the same filar pitch along the proximal section and the distal section.

In example 6, the lead of any of example 1-5, the inner tubular portion comprises a polymer coating on the inner coil conductor along the proximal section, the polymer coating does not extend along the curved section, and the inner polymer jacket does not extend over the inner coil conductor along the proximal section.

In example 7, the lead of any of examples 1-6, wherein the inner polymer jacket does not extend along the distal section.

In example 8, the lead of any of examples 1-7, wherein the inner polymer jacket is a tube and the inner coil conductor can move within the tube.

In example 9, the lead of any of examples 1-8, wherein the inner coil conductor is a unifilar coil.

In example 10, the lead of any of examples 1-9, further comprising an active fixation mechanism, the active fixation mechanism comprising a housing, an inner coupling located within the housing, and the active fixation element, the housing and the inner coupling having complementary threading and being rotatable relative to each other, the inner coupling connected to the inner tubular portion and the active fixation element, the housing connected to the outer tubular portion, the active fixation mechanism configured such that rotation of the inner tubular portion relative to the outer tubular portion extends and rotates the active fixation element for tissue fixation.

In example 11, the lead of any of examples 1-10, further comprising a proximal connector configured to interface with an implantable pulse generator, the proximal connector comprising a mechanism that can rotate the inner tubular portion relative to the outer tubular portion, wherein the inner tubular portion and the outer tubular portion are each connected to the proximal connector.

In example 12, the lead of any of examples 1-11, wherein the outer portion further comprises a ring electrode and an outer coil conductor, the outer coil conductor electrically connecting with the ring electrode.

Example 13 concerns an implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising: an outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section; an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner coil conductor extending from the proximal section to the distal section, the inner polymer jacket having a plurality of slots along the curved section that increases the flexibility of the inner tubular portion; and at least one electrical element in electrical connection with the inner coil conductor, the at least one electrical element configured to deliver electrical energy to tissue, wherein the inner tubular portion is rotatable relative to the outer tubular portion and the inner tubular portion is less stiff relative to the outer tubular portion along the curved section such that the curved shape is substantially maintained when the inner tubular portion is rotated relative to the outer tubular portion.

In example 14, the lead of example 13, wherein the inner tubular portion is stiffer along the proximal section than along the curved portion.

In example 15, the lead of either of examples 13 or 14, wherein: the inner tubular portion comprises a polymer coating on the inner coil conductor along the proximal section; the polymer coating does not extend along the curved section; and the inner polymer jacket does not extend along the proximal section.

In example 16, the lead of any of examples 13-15, wherein the inner coil conductor has a steeper filar pitch along the curved section than along the proximal section.

In example 17, the lead of any of examples 13-16, wherein the inner polymer jacket is a tube and the inner coil conductor can move within the tube.

In example, 18, the lead of any of examples 13-17, further comprising an active fixation mechanism, the active fixation mechanism comprising a housing, an inner coupling located within the housing, and an active fixation element, the housing and the inner coupling having complementary threading and being rotatable relative to each other, the inner coupling connected to the inner tubular portion and the active fixation element, the housing connected to the outer tubular portion, the active fixation mechanism configured such that rotation of the inner tubular portion relative to the outer tubular portion extends and rotates the active fixation element for tissue fixation.

Example 19 concerns an implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising: a outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section; an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner tubular member stiffer along the proximal section than the curved section, the outer tubular portion stiffer along the curved section relative to the inner tubular portion along the curved section such that the inner tubular portion can rotate relative to the outer tubular portion while the curved shape is substantially maintained; and an active fixation element on the distal end, the active fixation element in electrical connection with the inner coil conductor and configured to deliver electrical energy to tissue, the fixation element configured to affix to tissue by rotation of the inner tubular portion relative to the outer tubular member.

In example 20, the lead of example 19, wherein each of the inner tubular portion and the outer tubular portion are biased to assume a straight shape along the proximal section.

While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a schematic drawing of a cardiac rhythm management system.

FIG. **2** shows a schematic drawing of an implantable lead.

FIG. **3** shows a cross sectional drawing of an active fixation mechanism of an implantable lead.

FIGS. **4**A-B show cross sectional drawings of an implantable lead.

FIGS. **5**A-B show cross sectional drawings of an implantable lead.

FIG. **6** shows a coil conductor within a polymer jacket.

FIG. **7** shows a polymer jacket having a plurality of slots.

While the subject matter of this disclosure is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

FIG. **1** is a schematic drawing of a cardiac rhythm management system including a pulse generator **12** coupled to a lead **14** having a proximal end **16** and a distal end **18**. The pulse generator **12** can be implanted within a pocket formed in the patient's chest or abdomen. In various embodiments, the pulse generator **12** can be a pacemaker, an implantable cardiac defibrillator, and/or include both pacing and defibrillation capabilities. While the pulse generator **12** and lead **14** of FIG. **1** are configured and arranged for delivering cardiac therapy, various pulse generators and leads of the present disclosure may be configured and implanted for sensing bioelectrical activity and/or delivering electrical stimulus to various other targets within the patient.

The lead **14** can enter the vascular system through a vascular entry site formed in the wall of the left subclavian vein (not illustrated) and extend through the left brachiocephalic vein (not illustrated) and the superior vena cava **10** to access the patient's heart **20**. In the embodiment illustrated in FIG. **1**, the distal end **18** of the lead **14** extends into the right atrium **22** and is anchored by active fixation element **26** that penetrates a wall of the right atrium **22**. The active fixation element **26** can be a fixation helix configured to be screwed into tissue to chronically anchor the distal end **18** of the lead **14**. The active fixation element **26** can be electrically conductive for sensing and/or delivering stimulation at the anchor location. The distal end **18** of the lead **14** can have a bias to form the preformed curve **24**. The preformed curve **24** can allow the lead **14** to curve around to engage the atrial wall (e.g., proximate the bundle of His) after extending down the superior vena cava **10**. The preformed curve **24** can allow the lead **14** to have minimal stress within the lead **14** because the lead **14** is biased to assume a shape that fits at least part of the implant arrangement. For example, the components of the distal end **18** of the lead **14** may not resist, or may only minimally resist, being placed along the curved path of the lead **14** shown in FIG. **1**. Additionally, the preformed curve **24** can minimize the amount that the active fixation element **26** might have to pull on the tissue of the atrial wall to keep the lead **14** anchored.

FIG. **2** illustrates a schematic view of the lead **14**. The lead **14** can be biased to assume the shape shown in FIG. **2**. In particular, the lead **14** can be biased to assume different shapes along multiple sections of the lead. For example, the proximal section **32** of the lead **14** can be biased to assume a straight shape, the curved section **34** can be biased to assume the preformed curve **24**, and/or the distal section **36** can be biased to assume a straight shape. The overall shape of the lead **14** in FIG. **2** can be referred to as a J shape. As will be further discussed herein, the components of the lead **14** forming each of the proximal section **32**, the curved section **34**, and/or the distal section **36** can have mechanical biases to assume particular shapes. The aggregate mechanical biases of the components of each section can determine the overall shape of the section.

It is noted that even though the proximal section **32**, the curved section **34**, and/or the distal section **36** can each be biased to assume particular shapes, each section can nevertheless be flexible such that a force placed on the section can overcome the bias of the section to deform the section from the shape it otherwise assumes. In various embodiments, part or all of the proximal section **32** and/or part or all of the distal section **36** can be unbiased such that the section does not have a tendency to assume any particular shape (i.e. the section is fully compliant).

The lead **14** can include a proximal connector **30** configured to plug into the pulse generator **12** and/or an intermediate extension (not illustrated) to make a mechanical and electrical connection with the pulse generator **12**. The distal end **18** can include an electrode **40**. The electrode **40**, the active fixation element **26**, and/or any other electrical element on the lead **14** can connect with respective conductors extending within the lead **14** to electrically connect with one or more channels of the pulse generator **12**. The electrode **40**, the active fixation element **26**, and/or any other electrical element on the lead **14** can be configured for sensing bioelectrical signals and/or delivering stimulation energy. The electrode **40** can be a ring electrode. Alternative and/or additional electrodes can be provided along the lead **14** for sensing and/or stimulation.

FIG. **3** shows a cross sectional view of the distal tip **28** of the lead **14**. In particular, FIG. **3** shows an active fixation mechanism on the distal tip **28**. As shown, the active fixation mechanism comprises a housing **50**, a fixation element **26**, and an inner coupling **56**. The housing **50** can be formed from metal material and/or polymer material such as polyether ether ketone (PEEK). A proximal end of the housing **50** can be attached to a distal end of a polymer tube **52**. The polymer tube **52** can define an exterior surface of the lead **14** and can be formed from, for example, silicone or another material. The housing **50** can have an inner surface defining a circular interior. The housing **50** can have threading **54** along the inner surface. The inner coupling **56** can be contained within the circular interior of the housing **50**. The inner coupling **56** can be made from conductive metal. A distal end of the inner coupling **56** can be rigidly attached (e.g., via welding) to the active fixation element **26**. The inner coupling **56** can include threading on an exterior surface of the inner coupling **56** that is complementary to the threading **54** of the housing **50** such that the inner coupling **56** can be advanced and/or retracted within the housing **50** by relative rotation between the inner coupling **56** and the housing **50**. Such advancement of the inner coupling **56** can extend the active fixation element **26** from within the housing **50**. Rotation of the inner coupling **56** can rotate the active fixation element **26** to screw the active fixation element **26** into tissue.

A proximal end of the inner coupling **56** can be rigidly attached to an inner coil conductor **62**. For example, the inner coupling **56** can include a proximal projection dimensioned to fit within the lumen of the inner coil conductor **62**. The inner coil conductor **62** can additionally or alternatively be welded to the inner coupling **56**. The inner coil conductor **62** can electrically connect with a contact on the proximal connector **30**. In this way, electrical signals can be conducted between the pulse generator **12** and the active fixation element **26** via the inner coil conductor **62** and the inner coupling **56**. Further intermediary conductors can be included. In various embodiments, the inner coil conductor **62** can have a single filar which may have low heating advantages in an MRI environment.

The inner coil conductor **62** can extend along the lead **14** from the proximal connector **30** through the distal tip **28**. Because the inner coil conductor **62** can extend along the proximal section **32**, the curved section **34**, and the distal section **36** of the lead **14**, the inner coil conductor **62** can be divided into sections which correspond to the proximal section **32**, the curved section **34**, and the distal section **36**. The inner coil conductor **62** can have different mechanical properties along the proximal section **32**, the curved section **34**, and the distal section **36**, as will be further described herein.

As discussed herein, relative rotation between the inner coupling **56** and the housing **50** can extend and rotate the fixation element **26**. Being that the fixation of the active fixation element **26** into tissue will occur remote from the clinician (i.e. within the patient's body), the inner coupling **56** and the housing **50** may be required to be stabilized relative to one another such that one of the inner coupling **56** or the housing **50** can be rotated. The polymer tube **52** can stabilize the housing **50** by resisting rotation of the housing **50** by accepting torque from the housing **50**. The inner coil conductor **62** can rotate the inner coupling **56** by transferring torque to the inner coupling **56** or stabilize the inner coupling **56** by resisting rotation of the inner coupling **56** by accepting torque from the inner coupling **56**. In some embodiments, the inner coil conductor **62** can include an inner polymer jacket **60**, discussed further herein, which can in conjunction with the inner coil conductor **62** rotate the inner coupling **56** by transferring torque to the inner coupling **56** or stabilize the inner coupling **56** by resisting rotation of the inner coupling **56** by accepting torque from the inner coupling **56**.

The polymer tube **52** may be a part of an outer tubular portion that extends from the proximal connector **30** to the distal tip **28**, even though the polymer tube **52** may not extend the entire length of the lead **14**. Likewise, either of both the inner coil conductor **62** and the inner polymer jacket **60** may not extend along the entire length of the lead **14**, but may be a part of an inner tubular portion that extends from the proximal connector **30** to the distal tip **28**. The components of the outer tubular member, such as the polymer tube **52**, can be attached to one another such that they can control rotation of the housing **50** from the proximal end **16** of the lead **14**. Likewise, the components of the inner tubular member, such as the inner coil conductor **62** and the inner polymer jacket **60**, can be attached to one another such that they can control rotation of the inner coupling **56** and the active fixation element **26** from the proximal end **16** of the lead **14**. The outer tubular portion and the inner tubular portion are further described in connection with FIGS. **4A-5B**.

FIGS. **4A-B** show cross sectional views of the lead **14** at a location along the proximal section **32**. FIGS. **5A-B** show cross sectional views of the lead **14** at a location along the curved section **34**. FIGS. **4A-B** show that the lead **14** can be composed of an outer tubular portion **86** and an inner tubular portion **88** along the proximal section **32**. The inner tubular portion **88** and the outer tubular portion **86** are separated by space **80** to allow relative rotation. In some embodiments, one or more polymer tubes and/or other components may be provided along the space **80** between the inner tubular portion **88** and the outer tubular portion **86**.

A proximal end of the outer tubular portion **86** can be rigidly connected to a terminal ring (not illustrated) of the proximal connector **30**. The terminal ring can rotate relative to other components of the proximal connector **30**. The terminal ring can stabilize the outer tubular portion **86** by being kept from rotating (e.g., can be held in place) while the inner tubular portion **88** is rotated. A pin (not illustrated) on the proximal connector **30** can be rotated to rotate the inner tubular portion **88**.

The outer tubular portion **86** can include an outer polymer jacket **72** that defines an exterior surface **70** of the lead **14**. In some embodiments, the outer polymer jacket **72** can be a polyurethane tube. The type of material forming the outer polymer jacket **72** can change along the length of the lead **14**. For example, the outer polymer jacket **72** may be a polyurethane tube along the proximal section and the curved section **34**, and may transition to be a silicone tube along the distal section **36** (e.g., the outer polymer jacket **72** of FIGS. **4**A-**5**B may transition to the polymer tube **52** of FIG. **3**). The outer tubular portion **86** can include an outer coil conductor **74**. The outer coil conductor **74** can be a unifilar coil or can be composed of multiple filars (e.g., 3 or 4 filars). The one or more filars of the outer coil conductor **74** can be individually insulated in some embodiments, although such individual insulation is not shown in FIGS. **4**A-**5**B. The outer coil conductor **74** can conduct electrical signals between the proximal connector **30** and an electrical element on the distal end **18** of the lead **14**, such as the electrode **40**. In some cases, the outer polymer jacket **72** is heated over the outer coil conductor **74** during assembly to allow the outer polymer jacket **72** to at least partially flow over the filars of the outer coil conductor **74**. In this or another way, the outer coil conductor **74** may be mechanically fixed to the outer polymer jacket **72**. However, in some other embodiments the outer polymer jacket **72** and the outer coil conductor **74** are not directly mechanically coupled to each other, such that each of the outer polymer jacket **72** and the outer coil conductor **74** can have some degree of relative movement but can still move together when the outer tubular portion **86** is rotated.

The outer tubular portion **86** can comprise an insulating layer **76**. The insulating layer **76** may be formed from silicone. The insulating layer **76** may, among other things, provide electrical insulation between the outer coil conductor **74** and the inner conductor coil **62**.

The outer tubular portion **86** can also comprise a liner **78**. The liner **78** can be formed from a lubricious polymer, such as polytetrafluoroethylene (PTFE). The liner **78** can define an inner lumen of the outer tubular portion **86** inside of which can extend the inner tubular portion **88**. The lubricious properties of the liner **78** can reduce friction resulting from engagement between the outer tubular portion **86** and the inner tubular portion **88** during relative rotation.

Although the outer tubular portion **86** is illustrated in FIGS. **4**A-**5**B as being composed of the outer polymer jacket **72**, the outer coil conductor **74**, the insulating layer **76**, and the liner **78**, the outer tubular portion **86** can be composed by fewer, additional, and/or alternative components in various embodiments. For example, the outer tubular portion **86** may be composed of only the outer polymer jacket **72** and the outer coil conductor **74** in some embodiments. Moreover, some components may not extend for the entire length of the outer tubular portion **86**, such as the outer coil conductor **74**, the insulating layer **76**, and/or the liner **78**. The components of the outer tubular portion **86** can be loosely or tightly connected to one another as a single body such that that torque on one end of the outer tubular portion **86** can rotate the opposing end.

The mechanical properties of the inner tubular portion **88** can change along its length. For example, the inner tubular portion **88** may be relatively stiff along the proximal section **32** and relatively flexible along the curved section **34**. Greater flexibility along the curved section **34** can allow the inner tubular portion **88** to be rotated relative to the outer tubular portion **86** while the curve **24** of the curved section **32** is maintained. The inner tubular portion **88** can have different configurations (e.g., different materials and/or modifications to the materials) along the proximal section **32**, the curved section **34**, and the distal section **36** to provide the differences in mechanical properties, as further discussed herein.

The inner tubular portion **88** can include a polymer coating **64** over the inner coil conductor **62** along the proximal section **32** (as shown in FIGS. **4**A-B) and an inner polymer jacket **60** over the inner coil conductor **62** along the curved section **34** (as shown in FIGS. **5**A-B). The polymer coating **64** can be stiffer relative to the inner polymer jacket **60**. The inner polymer jacket **60** can have a thinner wall relative to the polymer coating **64**. A plurality of slots can be formed in the wall of the inner polymer jacket **60** to decrease the stiffness of the inner polymer jacket **60**. In some embodiments, the inner polymer jacket **60** may fit more loosely over the inner coil conductor **62** than the polymer coating **64**. The polymer coating **64** can be tightly integrated around and between the filars of the inner coil conductor **62**.

In some cases, either of the polymer coating **64** or the inner polymer jacket **60** can extend over the inner coil conductor **62** along the distal section **36**. The inner polymer jacket **60** and/or the polymer coating **64** can be formed from any of polyamide (e.g., Nylon), polyether block amide (PEBA), polyphthalamide (PPA), ethylene tetrafluoroethylene ETFE, PTFE, and/or other polymer material. The inner polymer jacket **60** can be a disposed over the inner coil conductor **62** as a coating or a tube. Although the inner tubular portion **88** is illustrated as being composed of the inner polymer jacket **60** and the inner coil conductor **62**, the inner tubular portion **88** can be composed of additional or alternative components in various embodiments. For example, one or more additional layers of polymer material can be provided along the inner tubular portion **88**, such as a layer extending within the lumen of the inner coil conductor **62**. The components of the inner tubular portion **88** can be loosely or tightly connected to one another as a single body such that that torque on one end of the inner tubular portion **88** can rotate the opposing end.

The inner tubular portion **88** and the outer tubular portion **86** can transfer opposing torque along the lead **14** from the proximal connector **30** to the distal tip **28** to extend and rotate the active fixation element **26**. However, the preformed curve **24** of the curved section **34** can frustrate relative movement of the inner tubular portion **88** and the outer tubular portion **86**. Specifically, if the inner tubular portion **88** and the outer tubular portion **86** defining the J-shape of the lead **14** must rotate relative to one another, then one of the inner tubular portion **88** and the outer tubular portion **86** must yield to the other during relative rotation, otherwise the shape of the preformed curve **24** may not be maintained. For example, the distal tip **28** may deflect widely as one curve would twist inside of another curve. Accurate placement of the active fixation element **26** at a target site would be difficult if the shape of the preformed curve **24** is not substantially maintained during extension and rotation.

Various embodiments of the present disclosure concern various configurations of the inner tubular portion **88** and the outer tubular portion **86** to allow relative rotation while substantially maintaining the preformed curve **24** of the curved section **34** (or other shape). In various embodiments, one of the inner tubular portion **88** and the outer tubular portion **86** can be biased to assume the shape of the preformed curve **24** while the other can be stiff enough to transfer torque yet flexible enough to yield to the bias shape of the other tubular portion. For example, in some embodiments, the outer tubular portion **86** is biased such that the lead **14** assumes the shape of the preformed curve **24** along the curved section **34** while the inner tubular portion **88** does not assume a bias shape (e.g., is fully compliant) along the curved section **34**. However, the inner tubular portion **88** can still be stiff enough to transfer torque along the lead **14** to extend and rotate the active fixation element **26**. In some embodiments, the outer tubular portion **86** and the inner tubular portion **88** can each be biased along the proximal section **32** such that the lead **14** assumes the straight shape of the proximal section **32** while the inner tubular portion **88** may not be biased along the curved section **34** to assume the preformed curve **24**. In this way, the inner tubular portion **88** can have variable stiffness along its length.

In various embodiments, any component of the outer tubular portion **86** can be configured to have mechanical bias to assume a particular shape such that the outer tubular portion **86** assumes the shape of the lead **14** along the proximal section **32**, the curved section **34**, and/or the distal section **36**. For example, the outer polymer jacket **72**, the insulating layer **76**, and/or the liner **78** may be heat set to assume a straight shape along the proximal section **32** and/or a curved shape along the curved section **34**. Other polymer and/or metal components of the outer tubular portion **86** can also be biased to assume these or other shapes.

The inner tubular portion **88** may contact the outer tubular portion **86** along the length of the lead **14** in various embodiments. This contact can create friction resistant to rotation of the inner tubular portion **88** relative to the outer tubular portion **86**. In some instances, the friction can be additive such that the proximal end of the inner tubular portion **88** must transmit enough torque to overcome the friction along the proximal section **32**, the curved section **34**, the distal section **36**, as well as overcome the friction within the active fixation mechanism. However, the inner tubular portion **88** along the curved section **34** may only have to transmit enough torque to overcome the friction in the curved section **34**, the distal section **36**, and the active fixation mechanism. Accordingly, the inner tubular portion **88** can be relatively stiffer along the proximal section **32** than along the curved section **34**. The polymer coating **64** along the proximal section **32** can stiffen the inner tubular portion **88**, however the polymer coating **64** may make the inner tubular portion **88** along the proximal section **34** too stiff to rotate within the outer tubular portion **86** while substantially maintaining the preformed curve **24**. Accordingly, in some embodiments, the polymer coating **64** may not be over the inner coil conductor **62** along the curved section **34**. In some embodiments, the polymer jacket **60**, which can be more flexible relative to the polymer coating **64**, can extend over the inner coil conductor **62** along the curved section **34**. In some embodiments, a plurality of slots can be formed in the wall of the polymer jacket **60** to increase the flexibility of the polymer jacket **60**.

In some embodiments, the mechanical properties of the inner tubular portion **88** can transition along its length (e.g., between the proximal section **32**, the curved section **34**, and/or the distal section **36**). For example, inner tubular portion **88** can be stiffer along the proximal section **32** relative to either or both of the curved section **34** and the distal section **36**. The material type, thickness, and/or provision of different features of the inner tubular portion **88** along the proximal section **32** may be different from the material type, thickness, and/or provision of different features of the inner tubular portion **88** along the curved section **32**. In some cases, the polymer coating **64** can extend along the proximal section **32** but not along the curved section **34** while the inner polymer jacket **60** can extend along the curved section **34** but not along proximal section **32**. In some embodiments, the inner polymer jacket **60** may be bonded to the polymer coating **64**. In such cases, the polymer coating **64** can be biased to assume a particular shape while the inner polymer jacket **60** may not be biased to assume a particular shape.

The inner coil conductor **62** can be straight during the coating process (e.g., extrusion), such that the polymer coating **64** heat sets to have a straight mechanical bias. The polymer coating **64** can then be stripped along a section of the inner coil conductor **62** that will extend along the curved section **34** of the lead **14**. Removal of the polymer coating **64** can significantly increase the flexibility of the inner tubular portion **88**, but may leave the inner coil conductor **62** insufficiently stiff to transfer enough torque along the lead **14** to overcome any friction opposing rotation and/or rotate the active fixation element **26** into tissue in some embodiments.

Several features can stiffen the inner coil conductor **62** along the curved section **34** to permit sufficient torque transfer. For example, the inner coil conductor **62** can be longitudinally stretched. The pitch of the filar pitch can be proportional to the stiffness of a coil, where a higher pitch corresponds to a stiffer coil and a lower pitch corresponds to a less stiff coil. Longitudinally stretching the inner coil conductor **62** along a particular section, such as along the section where the coating was removed, can increase the pitch of the filars along the section and consequently stiffen the section.

FIG. **6** shows a schematic view of the polymer coating **64** and the inner polymer jacket **60** along the inner coil conductor **62** at the transition from the proximal section **32** to the curved section **34** (e.g., in isolation from other components of the lead **14**). Following removal of the polymer coating **64** from the inner coil conductor **62** along the curved section **34**, the inner coil conductor **62** can be longitudinally stretched along the curved section **34**. In some embodiments, the inner coil conductor **62** can also be longitudinally stretched along the distal section **36**, as shown in FIG. **3**. In some cases, the filars of an unstretched section (e.g., along the proximal section **32**) can be arranged such that each filar turn contacts adjacent filar turns, which is referred to herein as a closed filar pitch. The filars of a longitudinally stretched section can be separated such that the filar of each turn does not contact the turns of adjacent filars, which is referred to herein as an open filar pitch. A section of closed filar pitch has a higher turns-per-unit-length measure (e.g., turns per inch) than a section of open filar pitch. For example, a closed filar pitch section can have about 4 times as many turns per unit length as an open filar pitch section.

In some embodiments, the polymer coating **64** can be applied over the full length of the inner coil conductor **62**. The polymer coating **64** can then be stripped away from the curved section **34** but left in place along the proximal section **32** and the distal section **36**. The inner coil conductor **62** can then be longitudinally stretched along the curved section **34**. In some embodiments, no additional polymer is provided directly over the longitudinally stretched inner coil conductor **62**. However, in some other embodiments, the inner polymer jacket **60** is provided directly over the stretched inner coil conductor **62**, replacing the stripped polymer coating. In some embodiments, the inner polymer jacket **60** can be provided as a tube that is slid over the curved section **34** of the inner coil conductor **62**. In some cases, the inner coil conductor **62** has a larger outer diameter than the inner diameter of the tube that is slid over the curved section **34**. In this case, the inner coil conductor **62** can be twisted or further stretched (below the elastic limit of the inner coil conductor **62**) along the curved section **34** to temporarily reduce the outer diameter of the inner coil conductor **62** to allow the tube to be slid over the curved section **34**. The inner coil conductor **62** can then be released to allow the outer diameter to radially expand to the inner diameter of the tube.

While an open filar pitch section of a conductor coil may have greater stiffness, the turns of the conductor coil may have a tendency to radially expand and/or unwind when torqued opposite to the filar pitch orientation. For example, if the active fixation element **26** has been screwed into tissue, but the implanting clinician decides to implant the distal tip **28** at a different location, then the inner tubular portion **88** can be turned in the opposite direction in which it was previously turned. However, friction within the lead **14** opposing rotation and/or resistance to unscrewing the active fixation element **26** can result in unwinding and/or radial expansion of the inner coil conductor **62** along where the inner coil conductor **62** is longitudinally expanded (e.g., along the curved section **34**), which can be counterproductive to unscrewing and/or can contribute to other issues.

The inner polymer jacket **60** can inhibit the expanded turns of the curved section **34** from unwinding and/or radially expanding beyond the circumference of the inner polymer jacket **60**. For example, if a clinician is turning the inner tubular portion **88** to back the active fixation element **26** out from tissue, and resistance to rotation along the inner coil conductor **62** urges the turns to radially expand, then the inner polymer jacket **60** can resist radial expansion of the inner coil conductor **62** along the curved section **34**. Provision of the inner polymer jacket **60** along the inner coil conductor **62** can also stiffen the inner tubular portion **88** along the curved section **34** to facilitate greater torque transfer.

In some cases, the inner polymer jacket **60** along the curved section **34** can be a tube that is not extruded over the inner coil conductor **62**, and is accordingly not heat set over the inner coil conductor **62** to take a particular shape (e.g., as opposed to extrusion or heat shrinking processes). The material forming the inner polymer jacket **60** along the curved section **34** can be of a different type than the material forming the inner polymer jacket **60** along the proximal section **32**. For example, the polymer coating **64** along the proximal section **32** may be stiffer than the inner polymer jacket **60** along the curved section **34**. Either of the polymer coating **64** and the inner polymer jacket **60** can be disposed over the inner coil conductor **62** by extrusion or heat shrink. In some cases, the inner polymer jacket **60** along the curved section **34** can have a different thickness than the polymer coating **64** along the proximal section **32**. For example, the polymer coating **64** can be thicker than the inner polymer jacket **60**. In some embodiments, the inner polymer jacket **60** has a thickness of about 0.001 inches.

FIG. **7** shows a schematic view of an inner polymer jacket **60**, according to various embodiments, in isolation from the other components of the lead **14**. As shown in FIG. **7**, the inner polymer jacket **60** can have a plurality of slots **90**. The plurality of slots **90** can be formed within the inner polymer jacket **60** along the curved section **34** to make the inner tubular portion **88** more flexible along the curved section **34**. The plurality of slots **90** can be arranged in a variety of patterns. In some embodiments, each slot extends around part of the circumference of the inner polymer jacket **60**. In some embodiments, each slot extends orthogonal to the longitudinal axis of the inner polymer jacket **60**. Slots oriented in this way can increase the flexibility of the inner polymer jacket **60** and can consequently increase the flexibility of the inner polymer jacket **60** along which the plurality of slots **90** extend. The plurality of slots **90** can be arrayed along the length of the inner polymer jacket **60**. The plurality of slots **90** can be equally spaced along the inner polymer jacket **60**. As shown in FIG. **7**, the plurality of slots **90** can form a winding pattern around the inner polymer jacket **60**. As shown in FIG. **7**, the ends of alternating slots **90** can be offset by a particular distance or angular degree such that the ends of the slots **90** wind around the inner polymer jacket **60**.

A pattern of slots can be formed in the inner polymer jacket **60** by various processes. In some cases, each slot can be mechanically machined from a polymer tube. For example, a spinning wheel can cut or grind each slot. In some cases, each slot can be formed by a laser removing or melting the polymer of each slot. In some embodiments, each slot is about 0.001 inches wide.

In some cases, the inner polymer jacket **60** along the curved section **34** can be the same polymer member as the polymer coating **64** that is applied over inner coil conductor **62** along the proximal section **32**. In such cases, the inner polymer jacket **60**, in coating form, can be slotted along the curved section **34** to selectively reduce the stiffness of the inner polymer jacket **60** along the curved section **34**.

Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

We claim:

1. An implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising:

an outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section;

an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner coil conductor extending from the proximal section to the distal section and having a steeper filar pitch along the curved section than along the proximal section, the inner polymer jacket having a plurality of slots along the curved section that increases the flexibility of the inner tubular portion; and

an active fixation element on the distal end, the active fixation element in electrical connection with the inner coil conductor, the active fixation element configured to affix to tissue by rotation of the inner tubular portion relative to the outer tubular member.

2. The implantable lead of claim **1**, wherein the outer tubular portion is stiffer than the inner tubular portion along the curved section such that the curved shape of the implantable lead is substantially maintained during rotation of the inner tubular portion relative to the outer tubular portion.

3. The implantable lead of claim **1**, wherein the inner tubular portion is relatively stiffer along the proximal section and less stiff along the curved portion.

4. The implantable lead of claim **1**, wherein the inner polymer jacket inhibits radial expansion of the inner coil conductor during rotation of the inner tubular portion.

5. The implantable lead of claim **1**, wherein the inner coil conductor has the same filar pitch along the proximal section and the distal section.

6. The implantable lead of claim 1, wherein:

the inner tubular portion comprises a polymer coating on the inner coil conductor along the proximal section; the polymer coating does not extend along the curved section; and

the inner polymer jacket does not extend over the inner coil conductor along the proximal section.

7. The implantable lead of claim 1, wherein the inner polymer jacket does not extend along the distal section.

8. The implantable lead of claim 1, wherein the inner polymer jacket is a tube and the inner coil conductor can move within the tube.

9. The implantable lead of claim 1, wherein the inner coil conductor is a unifilar coil.

10. The implantable lead of claim 1, further comprising an active fixation mechanism, the active fixation mechanism comprising a housing, an inner coupling located within the housing, and the active fixation element, the housing and the inner coupling having complementary threading and being rotatable relative to each other, the inner coupling connected to the inner tubular portion and the active fixation element, the housing connected to the outer tubular portion, the active fixation mechanism configured such that rotation of the inner tubular portion relative to the outer tubular portion extends and rotates the active fixation element for tissue fixation.

11. The implantable lead of claim 1, comprising a proximal connector configured to interface with an implantable pulse generator, the proximal connector comprising a mechanism that can rotate the inner tubular portion relative to the outer tubular portion, wherein the inner tubular portion and the outer tubular portion are each connected to the proximal connector.

12. The implantable lead of claim 1, wherein the outer portion further comprises a ring electrode and an outer coil conductor, the outer coil conductor electrically connected with the ring electrode.

13. An implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising:

an outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section;

an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner coil conductor extending from the proximal section to the distal section, the inner polymer jacket having a plurality of slots along the curved section that increases the flexibility of the inner tubular portion; and

at least one electrical element in electrical connection with the inner coil conductor, the at least one electrical element configured to deliver electrical energy to tissue, wherein the inner tubular portion is rotatable relative to the outer tubular portion and the inner tubular portion is less stiff relative to the outer tubular portion along the curved section such that the curved shape is substantially maintained when the inner tubular portion is rotated relative to the outer tubular portion.

14. The implantable lead of claim 13, wherein the inner tubular portion is stiffer along the proximal section than along the curved portion.

15. The implantable lead of claim 13, wherein:

the inner tubular portion comprises a polymer coating on the inner coil conductor along the proximal section;

the polymer coating does not extend along the curved section; and

the inner polymer jacket does not extend along the proximal section.

16. The implantable lead of claim 13, wherein the inner coil conductor has a steeper filar pitch along the curved section than along the proximal section.

17. The implantable lead of claim 16, wherein the inner polymer jacket is a tube and the inner coil conductor can move within the tube.

18. The implantable lead of claim 13, further comprising an active fixation mechanism, the active fixation mechanism comprising a housing, an inner coupling located within the housing, and an active fixation element, the housing and the inner coupling having complementary threading and being rotatable relative to each other, the inner coupling connected to the inner tubular portion and the active fixation element, the housing connected to the outer tubular portion, the active fixation mechanism configured such that rotation of the inner tubular portion relative to the outer tubular portion extends and rotates the active fixation element for tissue fixation.

19. An implantable lead having a proximal section, a distal section, and a curved section between the proximal section and the distal section, the implantable lead comprising:

a outer tubular portion extending from the proximal section to the distal section, the outer tubular portion defining an exterior surface of the implantable lead, the outer tubular portion having a bias such that the implantable lead assumes a curved shape along the curved section;

an inner tubular portion extending within the outer tubular portion, the inner tubular portion comprising an inner coil conductor and an inner polymer jacket over the inner coil conductor along the curved section, the inner tubular member stiffer along the proximal section than the curved section, the outer tubular portion stiffer along the curved section relative to the inner tubular portion along the curved section such that the inner tubular portion can rotate relative to the outer tubular portion while the curved shape is substantially maintained; and

an active fixation element on the distal end, the active fixation element in electrical connection with the inner coil conductor and configured to deliver electrical energy to tissue, the fixation element configured to affix to tissue by rotation of the inner tubular portion relative to the outer tubular member.

20. The implantable lead of claim 19, wherein each of the inner tubular portion and the outer tubular portion are biased to assume a straight shape along the proximal section.

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